STATEMENT AND RESOLUTION REGARDING PROPOSED REVISION OF FOOD AND DRUG ADMINISTRATION REGULATIONS CONCERNING DISEASE RELATED HEALTH CLAIMS ON LABELS*

COMMITTEE ON PUBLIC HEALTH AND THE COMMITTEE ON MEDICINE IN SOCIETY
The New York Academy of Medicine
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BACKGROUND

On October 29, 1985 the Food and Drug Administration (FDA) announced in the *Federal Register* its intent to publish a notice which would propose the agency's tentative approach for permitting truthful and nonmisleading health claims on food labels and related labeling, providing the claims can be substantiated with scientific evidence.[1] The notice will allow for public comment on the issue.

If such specific health claims were permitted on food labels, this would signal a major change in FDA policy. This decision could have significant influence on how the American public receives health information.

Beginning in 1971, the FDA permitted implicit health related food label claims; these concerned nutrition information such as the per serving content of calories or the content of various nutrients or cholesterol in food. However, a major change in labeling practice and content occurred in October, 1984 when the Kellogg Company, a major breakfast cereal manufacturer, decided to make *explicit claims* on a box of bran relative to cancer prevention. The printed material stated "Preventive health tips from the National Cancer Institute" and indicated that "Research may suggest that eating the right foods may reduce your risk of some kinds of cancer" and then made key recommendations such as "eat high fiber foods," "eat foods low in fat," "eat fresh fruits and vegetables" and "eat a well-balanced diet

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Address for reprint requests: The Committee on Public Health, The New York Academy of Medicine, 2 East 103rd Street, New York, N.Y. 10029

and avoid being over or under weight.'' All of these were on a box containing relatively high-fiber cereal together with the statement that ''That's why the healthy diet includes high fiber foods like bran cereal.'' Since this initial event, other similar claims have appeared in the marketplace both in food container labeling and in advertising.

Thus, the American public is faced with the potential for food labels that make widespread explicit health and disease specific claims with medical implications.

These claims must be viewed in the light of the pertinent sections of the Federal Food, Drug, and Cosmetic Act which states in part, ''A food shall be deemed to be misbranded if its labeling is false or misleading in any particular'' (Section 403). Section 201 states that ''The term 'drug' means. . . .articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.'' Section 505 requires that drugs must be both safe and effective for their intended purpose and Section 1019 of title 21 of the Code of Federal Regulations, which concerns nutrition labeling, states: ''A food label under the provisions of this section shall be deemed to be misbranded. . .if its labeling represents, suggests or implies that the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation or treatment of any disease or symptom.'' Hence, claims either to treat or to prevent some untoward effect, namely, disease, makes a product with that claim, in fact, a drug.

There are a number of companies in the food industry which are not engaged in promoting these types of disease related health claims. However, it is likely that all companies must be giving serious consideration to whether or not they should join this bandwagon which has opened up new avenues and opportunites in labeling and advertising. It is also obvious that this type of promotion appeals to the fears and concerns of many Americans about the possibility that either taking or omitting certain kinds of foods may have either a beneficial or deleterious effect on their health.

It is particularly a matter of concern when a branch of the federal government, namely, the National Cancer Institute, has given its imprimatur to this type of health claim. It is also of concern that the Federal Trade Commission—which is supposed to regulate truthfulness in advertising—agreed to let the Kellogg ad appear.

The goundswell in favor of these types of health claims has become so powerful that the Food and Drug Administration is now considering a review of its policies to determine what health claims are appropriate for labeling that

may be used by industry. If such claims were to be permitted, we may expect that claims in the future could include many types of nutrients and food components.

At the present time there is significant disagreement among nutritional and other scientists concerning the role of various food nutrients or other food components in the prevention of chronic diseases such as cancer, cardiovascular disease, and osteoporosis. The following is a brief review of some of these controversial associations.

"Fiber" Intake and Colorectal Cancer

With specific reference to "fiber" it is clear that this is a controversial area where human data are based on a hypothesis for which evidence is quite conflicting. Indicative of this situation is, on the one hand, the approval of the National Cancer Institute for the Kellogg health claim and, on the other hand, the report of the National Research Council's Diet, Nutrition and Cancer Report of 1982, which concludes: "The Committee found no conclusive evidence to indicate that dietary fiber (such as that present in certain fruits, vegetables, grains, and cereals) exerts a protective effect against colorectal cancer in humans. Both epidemiological and laboratory reports suggest that if there is such an effect, specific components of fiber, rather than total fiber, are more likely to be responsible.[2]

While some more recent studies suggest decreased risk of colon cancer with increased fiber, there are opposing findings. For example, in a community-based case-controlled study in Australia, men had increased relative risk with increased consumption of fiber. In those females with cancer who were consuming diets low in fiber (youngest cases), relative risk was increased as fat and protein increased; older women with more fiber in the diet were like men, i.e., an increasing risk with increasing fiber.[3]

The situation has been made more uncertain and hence more controversial by the fact that "fiber" is not a single substance but a variety of substances of different composition.

A recent study compared the effects of different fibers on colonic luminal pH, crypt cell proliferation, and colon carcinogenesis in rats given 1, 2 dimethylhydrazine. It was found that the yield of proximal colonic adenocarcinomas was significantly greater in the animals given oat bran, pectin, and guar (in large amounts) as compared to those on a fiber free diet.[4] The authors conclude: "Based on this and earlier reports in animals, it would seem timely to study the effects of dietary fibers on colonic epithelial cell

physiology in humans before embarking on large scale, long-term clinical colon cancer prevention trials using high fiber diets." This Committee suggests that, in addition, it would appear prudent to restrain those advertisers wishing to link their fiber products to cancer prevention.

Furthermore, there is some evidence that large amounts of certain "fibers" can cause morphologic changes in the rat jejunum and colon,[5] cause cell proliferative changes in the small[6] and large[7] intestine and increase the binding of certain ingested nutrients, especially calcium, but also copper, iron, and zinc, thus making them less available.[8]

Dietary Cholesterol and Coronary Artery Disease

Our understanding of the biochemical events in the disposition of cholesterol and triglycerides, the genetic basis of metabolic changes, and the influence of dietary factors as modifying influences on hyperlipidemia and the development of coronary heart disease are at a level far beyond our knowledge of biochemical, genetic, and dietary influences on cancer development. Nevertheless, epidemiologic and intervention studies in which dietary factors have differed or been modified have not been characterized by consistent findings in the populations studied or within the test populations.[9-11] Furthermore, experts in the field differ on their interpretation of some of the claims for the benefit of certain interventions and/or recommendations for dietary and other interventions. A recent spirited exchange in *Lancet* illustrates this point.[12-15]

This is an extremely active area of basic and clinical research. For example, direct angiographic evaluation of the coronary arteries of patients with stable angina was performed before and after two years on a vegetarian diet (P:S ratio 2 or more and cholesterol 100 mg/day). While a control group was not studied because of ethical considerations, 18 of 39 patients had no progression of their coronary artery obstruction but the remainder did.[16] Active investigations are underway on the possible value of monounsaturated fats and those from marine oils. The increasing knowledge about the biochemical pathways and underlying metabolic abnormalities[17] offers hope for fundamental advances in preventing coronary heart disease. Meanwhile, debate continues on the relative values of the public health approach versus concentrating on the identification and treatment of those at high risk.

Under these circumstances, it appears counterproductive for the FDA to allow label claims that a specific food with a certain amount of low cholesterol or fat will prevent coronary heart disease. Such claims may mis-

lead the public into believing in simplistic remedies for complicated disease processes involving many risk factors.

Calcium Intake and Osteoporosis

The Consensus Development Conference Statement from the National Institutes of Health[19] stated that osteoporosis is characterized by low bone mass. Recommendations designed to retard the osteoporotic process include estrogen replacement therapy, "adequate" calcium intake, and weight-bearing exercise. The efficacy of increased calcium intake and of weight bearing in *pre*menopausal women has support from some experiments, but it is still not settled, whereas these latter two strategies in treating *post*-menopausal women to decrease fractures remain without convincing experimental data despite individual reports.[19] That major differences exist among reputable scientists on the issue of calcium intake, bone density, and osteoporosis prevention or reversal approaches is illustrated by an exchange of letters on this subject[20,21] and a report of a recent meeting.[22] The clinical complexity of osteoporosis is discussed in a recent review.[23]

Equally critical to the issue of effectiveness of a proposed antiosteoporotic therapy is that of accuracy, reproducability, and predictive value of existing methods for measuring bone mass. While acknowledging major technical advances and with some optimism for further improvements and answers to currently elusive problems, Ott concludes her recent review with the statement "at this time, the use of these tests for screening postmenopausal women is premature, albeit profitable."[24]

From these examples, it is apparent that much more research is needed before definitive conclusions can be derived that will allow a consensus in the biomedical community as to whether a given class of foods, food supplements, or a specific nutrient is beneficial in preventing or minimizing the development of one or another so called chronic illness for a significant segment of the public.

The situation is made even more controversial and potentially misleading by the brand-specific relationship to the health claim on the food label. It will convey to the consumer the idea that the health benefit relates to the specific product in the food package.

How then can the FDA modify its policies in such a way that the consumer is protected against unwarranted, unproved claims? Dr. Forbes of the FDA has listed the various options which are available.[25] These are: abandoning regulation of claims, developing governmental approved generic claims, establishing voluntary guidelines, and prohibiting claims.

The first option is unacceptable since it would take us back to days when anything could be and was claimed on labels and in advertising; the ensuing problems led to passage of the FDCA. As for the second option, generic claims are unlikely to be adopted to any significant extent by the food industry even if approved by the FDA because they would not allow claims on behalf of a specific product. The establishment of voluntary guidelines as a third option is possible, and this seems to be the direction in which the current administration is leaning. This would then lead to the questions: "Who is going to establish voluntary guidelines and on what basis are they to be made?" If the FDA establishes a panel of "experts," that panel will have to deal with controversy because of the very nature of inadequate evidence in most of this field. It would have to decide on the accuracy or truth of a specific disease-related claim, hopefully in such a way that the claim would not be misleading and potentially harmful to the public. The ultimate loser will be the consumer if the best "guesses" of the expert panel prove to be incorrect. It would appear to this Committee that Dr. Forbes' fourth option is the desirable one at this time, i.e., not to change current regulations or their interpretation but rather to continue to prohibit specific disease-related health claims on labels.

Resolution

The Committee on Public Health of the New York Academy of Medicine resolves that:

Whereas, disease-related claims on labels or in advertising for foods, food supplements, and nutrients for possible protection against certain chronic illnesses may lead to widespread inadequate, inaccurate, or misleading claims to the public concerning such effectiveness and,

WHEREAS, such disease-specific labels are in violation of the word and spirit of the Food, Drug and Cosmetic Act,

THEREFORE, the Committee on Public Health urges the Commissioner of the Food and Drug Administration and the Secretary for Health and Human Services not to depart from established policy under the provisions of the Food, Drug and Cosmetic Act which prohibit specific health claims on labels of foods, food products, and food and nutrient supplements.

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